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Atty. Dkt. No 073406-0402

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jerry Pelletier, et al.

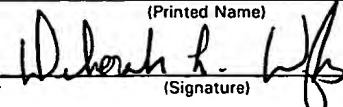
Title: DNA SEQUENCES FROM
BACTERIOPHAGE 77 THAT
ENCODE ANTI-MICROBIAL
POLYPEPTIDES

Appl. No.: 09/407,804

Filing Date: 9/28/1999

Examiner: R. Mitra

Art Unit: 1653

CERTIFICATE OF EXPRESS MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service's "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date below. Deborah L. Wykes (Printed Name)  (Signature) July 8, 2002

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PETITION TO THE COMMISSIONER UNDER 37 CFR 1.181 OR 1.182

Box DAC
Commissioner for Patents
Washington, D.C. 20231

Sir:

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OFFICE OF PETITIONS

Applicant hereby petitions the Commissioner to compel the Group Director of Technology Center 1600 to comply with the Notice provided in 1192 O.G. 68 allowing up to 10 independent nucleotide sequences to be claimed in one application. As appropriate, this petition may be considered as a petition under 37 CFR 1.181 to review a decision of a Technology Center Director (MPEP 1002.02(b)(15), a petition under 37 CFR 1.181 to invoke the supervisory authority of the Commissioner in a matter not otherwise provided for (MPEP 1002.02(b)(3), or a petition under 37 CFR 1.182 in a matter not otherwise provided for. In accordance with MPEP 1002.02(b) this petition is to be decided by the Office of the Deputy Commissioner for Patent Examination Policy.

The pending claims in the above-captioned application specify 6 nucleic acid sequences, with each sequence corresponding to a different open reading frame from Bacteriophage 77 (*Staphylococcus aureus* host). The Examiner in this case required the election of only one

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sequence for prosecution. Applicant objected to the restriction to one sequence, and requested that the Examiner comply with the Commissioner's Notice in 1192 O.G. 68 and compliance with the examination guidelines for examiners provided in MPEP 803.04.

The Commissioner's notice published as 1192 O.G. 68 states that:

[T]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirement of 37 CFR 1.141 and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

Accordingly, in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten (10).

In a telephonic interview with SPE Christopher Low, Applicant further discussed the restriction to one sequence. SPE Low confirmed that the examiners had been instructed to permit prosecution of only one sequence in an application, despite the instructions provided in 1192 OG 68 and MPEP 803.04. In a separate inquiry, it was confirmed that the instruction for the examiners to restrict applications to only one sequence was given by Technology Center 1600 Director John Doll.

In objecting to the Examiner's restriction to a single sequence, Applicant pointed out that the present case is in no way exceptional in the sense mentioned in 1192 O.G. 68. In response to this argument, the Examiner merely reiterated the observation that the 6 specified sequences encoded different polypeptides. However, this is precisely the type of situation for which the Notice indicates that up to 10 sequences will be permitted. As shown in the portion of the Notice quoted above, it is intended to normally allow up to 10 independent sequences, *i.e.*, sequences that encode different polypeptides, to be prosecuted in a single application.

During the telephonic discussion referenced above, SPE Low stated that the Group had instituted the "one sequence" policy in order to reduce the time needed for sequence searching.

However, this is irrelevant. Instead, the issue is whether examiners in Technology Center 1600 will or will not follow valid, current notices from the Commissioner.

With the current instructions to examiners in Technology Center 1600 to restrict applications to only one sequence, Technology Center 1600 has usurped the Commissioner's authority, and directly contravened 1192 O.G. 68. Further, the restriction to one sequence is directly contrary to the policy of encouraging biotechnology in the United States as stated in 1192 O.G. 68. To the contrary, the restriction to only one sequence acts as a blockade to the ability of small biotech companies and individuals to obtain useful patent protection on inventions for which the claims specify nucleic acid sequences. Indeed, the policy of encouraging development of biotechnology is particularly important in the current environment of reduced investment. Therefore, maintenance of the policy and practice of allowing up to 10 independent sequences, as embodied in 1192 O.G. 68, is very important to development of the biotechnology industry.

Failure to reverse the unauthorized practice of Technology Center 1600 in restricting applications to only a single sequence will simply prevent biotech companies from obtaining patent protection on many otherwise patentable inventions, thereby significantly impairing biotechnology development.

In view of the facts and discussion above, Applicant respectfully requests that the instructions to the examiners in Technology Center 1600 be reversed, and that Applicant be allowed to prosecute up to 10 independent sequences in this application in accordance with 1192 O.G. 68 and MPEP 803.04.

A check in the amount of \$130.00 in accordance with 37 CFR 1.17(h) is enclosed. If any additional fee is due, or if the amount enclosed is incorrect, kindly charge or credit Deposit Account 50-0872 for the appropriate amount.

Respectfully submitted,

Date 8 July 2002

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